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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,131	09/10/2003	Roy L. Barrus	20518/54	3557
7590	02/25/2005		EXAMINER	
Mark S. Leonardo, Esq. Brown Rudnick Berlack Israels LLP One Financial Center Boston, MA 02111			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/659,131	BARRUS ET AL.
Examiner	Art Unit	
Catherine S. Williams	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 22 November 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,3-5,14-17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (US Pat# 5,997,504) in view of Sturman (USPN 5,215,525).

Bell discloses a safety shield apparatus including needle (16,18) and a shield (see figures 12A-12C). The shield includes at least one elongated part with a proximal end mounted with the proximal portion of the needle and a distal end mounted with a planar contact surface (120). The shield is shown being extensible between a retracted position and an extended position via relative movement between the surface (120) and the proximal portion of the shield (see figures 12A-12C). The device further includes a needle hub (104), an appendage wing (44), segment (28) and channel (inside 28). A latch (112) is shown in figure 12D with an arm having a plurality of surfaces including an arcuate surface. The needle is angularly displaced approximately 90 degrees (see figure 4A). The contact surface includes an opening (132) and a pad (122) which is an adhesive cushion. A cushion is considered to be a material that is felted, breathable and configured for wicking moisture. The distal end of the shield is hingedly attached to the contact surface (see figures 12A and 12B). A first surface of the pad is connected to the contact surface. A second surface of the pad is connected to the patient's skin. See figures 12A-12C. The pad has a planar surface with a thickness and a peripheral surface connecting the first

and second surfaces. See figures. The pad is permanently attached to the device in that is in not specifically designed to be removed or to be changed.

Bell meets the claim limitations as described above but fails to include a needle bearing in the planar contact surface that slidably engages the needle.

Sturman discloses a needle shield for a slidably retractable needle. The distal tip of the shield housing includes a needle bearing (50,52 see figure 6). This closure prevents longitudinal movement of the pointed distal end of the needle.

At the time of the invention, it would have been obvious to incorporate the needle bearing of Sturman into the invention of Bell. Both devices are analogous in the art of needle shields and both work by sliding the needle proximally into a needle housing/shield. One skilled in the art would recognize the advantages of the structure of Sturman as preventing further contact with the distal end of the needle. Furthermore, one skilled in the art would have incorporated the bearing into the opening in the planar contact surface of Bell in order to reduce the chance of further contact with the retracted needle tip and prevent accidental needle sticks.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,6-7,9-13 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell in view of Sturman in further view of Buttaravoli (US Pat# 3,918,446). Bell in view of

Sturman meets the claim limitations as described above but fails to include the pad being made from a foam material and having an antimicrobial agent or a thin film coating.

However, Buttaravoli discloses a securement device for intravenous catheters that includes a pad (12) that includes a foam with a thin film adhesive. The pad includes a bacteriostatic or bacteriocidal chemical. See 3:48-67. The pad also includes a slit (16) and a groove (24). The pad is a disk shape. See figures. As shown in figure 3, a friction fit occurs between the needle and the pad. The pad also includes a through hole (20).

At the time of the invention, it would have been obvious to substitute the entirety of the pad of Buttaravoli for the pad of Bell in view of Sturman. The motivation for the incorporation is taught by Buttaravoli in that the pad having a bacteriocidal chemical insulates the incision from a major source of infection be a physical and chemical barrier. See 3:65-67. By incorporating the pad of Buttaravoli, the device of Bell in view of Sturman decreases the chance of infection to the patient.

Claims 7-8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bell in view of Sturman in further view of Hodgson (US pat# 3,645,835). Bell in view of Sturman meets the claim limitations as described above but fails to include a thin film perforated coating on one of the surfaces of the pad.

However, Hodgson discloses a moisture-vapor-permeable pressure sensitive adhesive. This adhesive (thin film coating). The adhesive may have perforations. See 4:12-14. The advantages of the adhesive of Hodgson include preventing ingress of bacteria. See 3:5+.

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At the time of the invention, it would have been obvious to substitute the adhesive of Hodgson for the adhesive of Bell in view of Sturman. The motivation for the incorporation is taught by Hodgson. See 3:5+. By incorporating the adhesive of Hodgson, the device of Bell in view of Sturman decreases the chance of infection to the patient.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15,22,23,24 and 26 of copending Application No. 10/016,276. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant case is a broad recitation of the device claimed in application 10/016,276.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571-272-4970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *(Signature)*
February 18, 2005

Nicholas D. Lucchesi
NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700